

K102277

3. 510(k) SUMMARY

OCT 6 2010

510(k) SUMMARY [as required by section 807.92(c)]

510(k) Owner's Name: Vertebral Technologies, Inc.

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Name of Contact Person: Suresh Ghai, Ph.D.
VP, Quality and Regulatory Affairs

Date prepared: 10 August, 2010

Trade or Proprietary Name: InterFuse® T - Intervertebral Body Fusion Device

Common or Usual Name: Intervertebral Body Fusion Device

Classification Name: Intervertebral Fusion Device with Bone Graft, Lumbar
21 CFR § 888.3080
Product code: MAX
Device Class: II

3.1 LEGALLY MARKETED DEVICE TO WHICH YOUR FIRM IS CLAIMING EQUIVALENCE

The modified InterFuse® T - Intervertebral Body Fusion Device is substantially equivalent in performance, indication, design and material to VTI's own InterFuse® Intervertebral Body Fusion Device cleared under Premarket notification # K 091988.

3.2 DEVICE DESCRIPTION

VTI's InterFuse® T - Intervertebral Body Fusion device is made of implant grade PEEK-OPTIMA® (Poly ether ether ketone), a polymer with a history of use in interbody fusion device designs, and which has a compressive modulus similar to bone. Each segment of the device has embedded tantalum beads that aid in visualizing the implanted device under x-ray. Each segment has an integral rail and/or slot which slide through or over the rail or slot in the adjacent segment to complete the device. Each segment incorporates a ramp lock to help ensure that it is properly aligned and engaged with the adjacent segment. The exposed rail of the segments is removed after the middle segment is installed. Each segment has a vertical slot through the

device for the surgeon to fill with autogenous bone that will provide a path for solid bone growth during the fusion process. The device is produced in four heights (8, 10, 12 and 14 mm) each for parallel and 10° lordotic configurations to fit the angular geometry of the disc at each disc level. The Anterior – Posterior (AP) length of the device is 24 mm. The middle segment (B) comes in two widths (9 mm or 10 mm).

3.5 INTENDED USE OF THE DEVICE

The InterFuse® T - Intervertebral Body Fusion Device is indicated for intervertebral spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The InterFuse T device is to be used in patients who have had at least six (6) months of non-operative treatment. These patients may have had a previous non-fusion surgery at the involved spinal level(s). The InterFuse T device is indicated for use with autogenous bone graft and to be used with supplemental internal spinal fixation systems that have been cleared for use by the FDA in the lumbosacral spine.

3.6 TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICE

InterFuse® T - Intervertebral Body Fusion Device is substantially equivalent in performance, indication, design and materials to InterFuse® Intervertebral Body Fusion Device from our company (VTI), cleared under premarket notification # K091988.

3.7 SUMMARY AND CONCLUSIONS FROM THE NONCLINICAL TESTS SUBMITTED

The substantial equivalence is supported by bench testing comparing the InterFuse® T Intervertebral Body Fusion Device to the predicate device (K091988).

The basic design of the device has not changed from the 510(k) cleared device (K091988). The device will be assembled (intra-operatively) via Transforminal Lumbar Interbody Fusion (TLIF) technique as compared to the un-modified device which is assembled (intra-operatively) via Unilateral Posterior Lumbar Interbody Fusion (UPLIF) technique.

The InterFuse T Intervertebral Body Fusion Device (the modified device) is assembled (intra-operatively) using the same rail and slot system as done for unmodified InterFuse IFD (K091988).

The performance of the modified device (InterFuse T) was tested, post gamma irradiation sterilization, in accordance with ASTM F2077-03 and ASTM 2067 – 04 as detailed below:

- a. Device durability was verified by static and dynamic compression testing per ASTM F2077-03.
- b. Device durability was also verified by static and dynamic compression shear testing per ASTM F2077-03.
- c. Static Expulsion testing.
- d. Subsidence testing was conducted per ASTM F2267-04.

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Substantial equivalence comparison between InterFuse T and InterFuse P (predicate device) performance results is given in section 10.

The detailed performance results are given in section 11.

The packaged and sterilized InterFuse T device was also tested for cytotoxicity (per ISO 10993-5:2009) and was found to be non-toxic.

There is no change to the packaging (materials, packaging configuration, sealing equipment, sealing parameters), sterilization process or sterility assurance level.

On the basis of performance data it is concluded that the modified device (InterFuse T – Intervertebral Body Fusion Device) is substantially equivalent to the unmodified InterFuse device (K091988).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

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OCT 6 2010

Re: K102277

Trade/Device Name: InterFuse® T Intervertebral Body Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: September 13, 2010
Received: September 14, 2010

Dear Dr. Ghai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may; therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

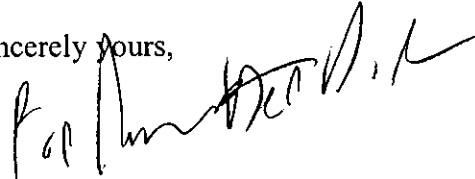
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act.

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. STATEMENT OF INDICATION FOR USE

Indication for Use

510(k) Number (if known): K102277

Device Name: InterFuse® T - Intervertebral Body Fusion Device

Indications for Use:

The InterFuse® T - Intervertebral Body Fusion Device is indicated for intervertebral spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The InterFuse T device is to be used in patients who have had at least six (6) months of non-operative treatment. These patients may have had a previous non-fusion surgery at the involved spinal level(s). The InterFuse T device is indicated for use with autogenous bone graft, and to be used with supplemental internal spinal fixation systems that have been cleared for use by the FDA in the lumbosacral spine.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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